

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA, STATES
OF CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS,
VERMONT, AND WASHINGTON; THE
COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA; and
THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN RESEARCH
& DEVELOPMENT, LLC, and JOHNSON &
JOHNSON,

Defendants.

Civil Action No. 19-12107 (MEF)(SDA)

Document Electronically Filed

Hon. Michael E. Farbiarz, U.S.D.J.

Hon. Stacey D. Adams, U.S.M.J.

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION
TO RELATOR'S NOTICE OF OBJECTIONS TO SPECIAL MASTER ORDER (ECF
NO. 422) RELATED TO *IN CAMERA* REVIEW OF DOCUMENTS NOT SUBJECT
TO PRIVILEGE PURSUANT TO THE CRIME-FRAUD EXCEPTION AND MOTION
FOR FURTHER *IN CAMERA* REVIEW**

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PRELIMINARY STATEMENT

Relator's instant motion (ECF No. 424) marks the third time he has asked for *in camera* review of the same body of privileged documents pursuant to the crime-fraud exception. Relator's motion should be denied. The Special Master appropriately determined that Relator's allegations do not satisfy the evidentiary standard for *in camera* review and, nevertheless, after carefully reviewing the 50 documents Relator deems "most important," the Special Master found "*no evidence* that Defendants were engaged in, committing or intending to commit a fraud or crime, or that Defendants' attorney-client communications were being misused in furtherance of any fraud or crime." ECF No. 422 at 2–3 (emphasis added).

In his objections to that Order, Relator alleges no particular error in the Special Master's review of these 50 documents or in the Special Master's conclusion that they contain no evidence of fraud. Instead, Relator simply purports to "incorporate by reference" his earlier brief to this Court, in which he asked this Court to direct the Special Master to review the 50 documents in the first place.

For all the reasons set forth in Defendants' previous Response to that brief (ECF No. 414), Relator's allegations of fraud are both legally and factually deficient. If the Court accepts Relator's invitation to consider his prior brief as "incorporated by reference,"¹ Defendants ask the Court to consider their prior response (ECF No. 414) in tandem, and Defendants will not repeat those arguments here. Instead, Defendants write to make three points:

¹ The Court should not. Relator's attempt to "incorporate" his objections to Judge Arpert's prior order is improper twice over. First, it fails to offer any specific objection to the Order at issue here. *See infra* 7–8. Second, Relator's incorporation of his prior 30-page brief is an improper attempt to skirt this Court's ordinary page limits for briefs. *See* L. Civ. R. 7.2; *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 376 (D. Del. 2014) ("Underlying briefs cannot be 'incorporated by reference' as a way of avoiding the page limits on objections to a [Special Master]'s orders and reports."). Nor should Relator be permitted any further reply relating to the arguments raised in those briefs.

First, Relator failed to meet the evidentiary standard for *in camera* review in the first place and the Special Master completed an *in camera* review of Relator’s 50 priority documents anyway (*see* ECF No. 417), finding no evidence of fraud. Relator has already gotten the relief he sought, and Relator identifies nothing else that reasonably should be done at this point. By asking this Court to re-review all 50 priority documents again, without making any specific objection as to the Special Master’s process for reviewing the documents or his conclusion that they contained “no evidence” of fraud, Relator’s position renders the job of the Special Master entirely superfluous and a waste of this Court’s time and resources.

Second, Relator is wrong to rely on *In re Abbott Laboratories*, 96 F.4th 371, 381 (3d Cir. 2024), which the Special Master correctly determined is inapposite. ECF No. 374 at 18. In that case, the Third Circuit upheld the production of documents pursuant to the crime-fraud exception where a court had *already* held, following a bench trial in a prior, distinct litigation, that a “sham litigation” occurred. *Abbott Labs.*, 96 F.4th at 377, 381. Here, by contrast, Judge McNulty has *twice* ruled that Defendants’ assertion of the patent was *not* fraudulent, *infra* at 8–9, and Relator concedes he is not pleading a “sham litigation” in this case, ECF No. 424-1 at 12.

Third, Relator’s ever-evolving demands of this Court and the Special Master—repeatedly revising his theories of fraud and his “priority” lists of documents—make clear that his motions are nothing more than “groundless fishing expeditions” that should be denied. *United States v. Zolin*, 491 U.S. 554, 571 (1989).

BACKGROUND

Throughout three years of discovery in this case, Defendants produced more than 134,000 documents, totaling over six million pages. Over 14 months after Defendants substantially completed their productions and served their privilege logs—and with just one month left in fact discovery—Relator moved for *in camera* review of 965 privileged documents. Importantly, all of

the privileged documents post-date the alleged false statements that are the gravamen of Relator’s complaint. Relator alleges that Defendants made false statements in their June 4, 2013 submission to the U.S. Patent & Trademark Office (“USPTO”) regarding the commercial success of their prostate cancer drug Zytiga in combination with prednisone in order to obtain the disputed patent, which relates to that drug. The privileged communications Relator seeks all come *after* that submission was made.

Judge Arpert’s October 4, 2024 Order. Following briefing and oral argument on the record,² the Special Master denied Relator’s motion in a thorough and well-reasoned order. *See* ECF No. 374. Judge Arpert concluded that Relator had “not met his burden of establishing a factual basis adequate to support a good faith belief by a reasonable person . . . that the crime-fraud exception applies.” *Id.* at 13. At the outset, “[f]or purposes of deciding [this] Motion only,” the Special Master first held that Relator did not meet his evidentiary burden to show that Defendants’ arguments to the USPTO regarding Zytiga’s commercial success contained evidence of fraud that would justify *in camera* review. *Id.* at 15–16. Relator misconstrued documents discussing the challenges of *marketing* Zytiga’s FDA-required label indication—the co-administration of abiraterone and prednisone—and argued that they demonstrate Defendants’ lack of belief in the *therapeutic efficacy* of that combination therapy. But, as the Special Master determined, Relator had not identified any evidence to support that remarkable extrapolation. Rather, as the Special Master stated, “considerable testimony” shows that a “distinction” must be drawn between “the marketing of Zytiga” (*i.e.*, the “weakness” or challenge of marketing a drug required to be co-administered with prednisone, a steroid, to a class of doctors, urologists, who traditionally avoid prescribing steroids) and “the therapeutic and clinical benefits of Zytiga” (*i.e.*, the “strength”

² Relator’s prior briefing and statements at argument are essentially the same as those he makes to the Court now, and he has already been heard on these issues. *See* Hr’g Tr. (Sept. 19, 2024).

reflecting the novel and powerful efficacy of Zytiga co-administered with prednisone). *Id.* at 16.

Next, the Special Master rejected Relator's claims that Defendants committed fraud by listing the '438 Patent in the *Orange Book* and commencing patent infringement litigation to enforce the '438 Patent as "unavailing." *Id.* First, the Special Master observed that those theories "fall outside the claims set forth in Relator's pleading." *Id.* Second, the Special Master found that the theories were "rejected in prior litigation" by Judge McNulty and are "refuted by evidence in the record." *Id.* Finally, the Special Master held that Defendants' listing of the patent in the *Orange Book* and initiation of litigation against generic competitors were "somewhat attenuated with respect to the fraud that is alleged by Relator" (*i.e.*, purported false statements to the USPTO). *Id.* As a result, the Special Master found that Relator had "not persuasively established a 'logical link'" between the allegedly fraudulent statements to the USPTO and the privileged communications that post-date those statements. *Id.* at 17.

The Special Master also rejected Relator's arguments that Defendants' long range financial planning (LRFP) documents evidenced fraud whenever they did not assume that the '438 Patent would prevent generic competition until its expiry. As he stated, the mere fact that "LRFPs do not assume generic competition until the '438 Patent's expiration in 2027 does not establish J&J knew or believed that the '438 Patent was obtained by fraud." *Id.* Judge Arpert found Relator's contrary theory—which assumes away the reality that planning for a range of future scenarios is simply sound and prudent business practice—to be too "speculative." *Id.* Moreover, even if the LRFPs could be considered "evidence" of the alleged fraud, they were not communications made in "furtherance" of the fraud, as the law requires. *Id.* That is, they were entirely *internal* communications used for *internal* financial planning purposes. But Relator offers no evidence tying those documents to the acts that allegedly furthered the alleged fraud—*i.e.*, listing the '438 Patent in the *Orange Book* or asserting the '438 Patent in litigation. Nor were the communications

used to support allegedly false statements to any third party, including the USPTO or the government healthcare programs that made payments relating to Zytiga.

Finally, apart from the deficiencies in Relator's legal theories, the Special Master also denied Relator's Motion based on its excessive breadth. *See id.* at 18. Relator sought *in camera* review of over 900 documents spanning thousands of pages, yet did not argue or establish in his Motion that any of them was "relevant." *Id.* Relator's subsequent request for "priority" *in camera* review of a shorter list of 200 documents remained excessively "broad" because "Relator provided no rationale as to why or how those 200 documents were selected or identified." *Id.*

This Court's December 10, 2024 Order. Relator objected to the Special Master's order. Relator narrowed his request and asked this Court to direct the Special Master to review a set of 50 "priority" documents in the first instance, before assessing whether further review was warranted. ECF No. 394 at 30. This Court then issued an order instructing the Special Master to review the 50 priority documents and "then make a determination as to whether the remaining documents need to be reviewed and whether his original Order still stands." ECF No. 417 at 2.

Judge Arpert's January 31, 2025 Order. The Special Master next conducted a "careful review" of the 50 priority documents identified by Relator. ECF No. 422 at 3. In his Order, the Special Master found "no evidence that Defendants were engaged in, committing or intending to commit a fraud or crime, or that Defendants' attorney-client communications were being misused in furtherance of any fraud or crime." *Id.* In addition, the Special Master "discern[ed] no basis to conduct any further review of the larger body of documents previously identified by Relator for *in camera* review." *Id.*

Relator's Objections. Relator objects to the Special Master's order and asks this Court to re-do all of the Special Master's work by conducting a "*de novo*" *in camera* review of the 50 priority documents the Special Master has already reviewed. ECF No. 424-1 at 14. In addition, if

the Court identifies evidence of fraud in even one of the 50 documents already reviewed by the Special Master, Relator asks the Court to review the broader universe of 965 privileged communications. At the end of that process, Relator seeks the production of any privileged communications that the Court determines fall within a list of six categories of documents allegedly involving communications between and among Defendants' legal counsel demonstrating their knowledge that their statements to the USPTO were false, or relating in any way to Defendants' subsequent decision to exercise their lawful patent rights (a theory that falls wholly outside of Relator's complaint). *See id.* at 13–14.

As demonstrated by Defendants' prior briefing, and confirmed by the Special Master's review, no such communications exist. Relator's claim that Defendants prosecuted the patent with fraudulent intent is based entirely on conjecture and therefore lacks any evidentiary basis. It also is plainly refuted by Judge McNulty's conclusions in the underlying patent litigation.

ARGUMENT

Relator's objection should be denied for all the reasons explained more fully in the Special Master's Orders and Defendants' earlier brief. *See* ECF No. 414.

First, as the Special Master found, Relator's new theories of liability "fall outside the claims set forth in Relator's pleading." ECF No. 374 at 16. Relator's Complaint offers no particularized allegations supporting his new allegations that Defendants acted with fraudulent intent when listing the patent in the *Orange Book* or when Defendants asserted it in litigation pursuant to the statutorily approved process set forth in the Hatch-Waxman Act. *Id.* Thus, whatever evidence Relator claims to adduce to support these new theories, they are procedurally "barred" because they are not set forth with particularity in the Complaint. *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 676 F.3d 318, 326 (3d Cir. 2012).

Second, even if Relator's new theories were properly pled, the Special Master correctly

held that Relator failed to satisfy the evidentiary standard necessary to justify *in camera* review in the first place. *See* ECF No. 374. Now that the Special Master has already reviewed the 50 “most important” documents anyway, finding “no evidence” of fraud, ECF No. 422, that should end the analysis.

Finally, Relator’s request is excessively broad. Although Relator seeks *in camera* review of a “priority” tier of 50 documents in the first instance, he continues to ask the Court ultimately to review all of the 965 privileged documents at issue—an unreasonable number, especially in light of Relator’s failure to adduce actual evidence of fraud in three years of discovery. ECF No. 424-1 at 14. Moreover, Relator unnecessarily filed his motion (ECF No. 346) at the eleventh hour—more than 14 months after Defendants substantially completed their document productions and served their privilege logs.

In addition, three points from Relator’s most recent objections merit a response.

I. Relator fails to identify any specific legal or factual error that the Special Master made in his review of the 50 priority documents.

Relator specifies no particular error in the Special Master’s review process and no particular error in his conclusion that the 50 priority documents contained “no evidence” of fraud. Nevertheless, Relator insists that this Court must “perform its own *in camera* review” of the same documents “*de novo*.” ECF No. 424-1 at 2.

Relator should not be entitled to a do-over without specifying some alleged factual or legal error in the Special Master’s process, review, or reasoning. Relator’s request otherwise undermines the Special Master’s office and the efficiencies it is designed to achieve. *See Luppino v. Mercedes Benz USA, LLC*, No. 2:09-cv-05582-DMC, 2013 WL 5025229, at *3 (D.N.J. Sept. 11, 2013) (The function of a special master is “to perform some other time consuming or detailed tasks that the district court judge or a magistrate judge would be less efficient in accomplishing.”

(cleaned up)); *see also* ECF No. 331 (explaining the reasons for appointing the Special Master).

For this reason, a court reviewing a special master's order will often limit its analysis to *only* those aspects of an order to which a specific objection was made. *See, e.g., In re Johnson & Johnson Deriv. Litig.*, No. 10-2033, 2013 WL 6163858, at *4 (D.N.J. Nov. 25, 2013) (“I acknowledge that it is the role of this Court to review *de novo* the Special Master's conclusions of law and fact. . . . [I]n this Opinion, I will only address the specific objections raised by the parties.”); *USAA Mutual Funds Tr. v. Valeant Pharms. Int'l, Inc.*, No. 20-cv-07462-MAS, 2021 WL 1306196, at *2 (D.N.J. Feb. 26, 2021) (“The Undersigned shall perform a *de novo* review of those portions to which a specific objection is made and may accept, reject, or modify, in whole or in part, the [report and recommendation].”). Indeed, some courts will refuse to consider objections to a Special Master's Report that fail to identify any specific factual or legal errors. *See, e.g., Wolverine World Wide, Inc. v. Am. Ins. Co.*, No. 1:19-cv-10, 2022 WL 1222656, at *1 (W.D. Mich. Apr. 26, 2022) (“For an objection to be sustained, it must specifically identify a factual or legal error in the report and recommendation, which undermines the conclusions and recommendations therein. General objections do not satisfy the objection requirement.” (cleaned up)). That is the appropriate course for this Court to take here.

II. Relator's reliance on *Abbott Laboratories* is misguided.

Relator relies heavily on *Abbott Laboratories*, ECF No. 424-1 at 10–14, but the Special Master rightly concluded that case is inapposite, ECF No. 374 at 18. In *Abbott Laboratories*, the Third Circuit considered a petition for a writ of mandamus from a district court order compelling the production of privileged documents pursuant to the crime-fraud exception. 96 F.4th at 375. The purchaser lawsuit in the district court alleged that a branded drug manufacturer had engaged in a “sham litigation” by suing generic drug manufacturers in an earlier patent lawsuit based on “objectively baseless” legal claims. *Id.* at 377. The district court held that “sham litigation [i.e.,

the underlying patent lawsuit] triggers the crime-fraud exception,” and the Third Circuit concluded that this decision was not a “clear and indisputable abuse of discretion or error of law.” *Id.* at 381. The Third Circuit emphasized that its focus was “limited to what qualifies as ‘sham litigation’” and that “[c]ertainly not *all* frivolous litigation falls within the crime-fraud exception.” *Id.* at 381–82.

As the Special Master correctly determined, *Abbott Laboratories* is readily distinguishable. ECF No. 374 at 18. In *Abbott Laboratories*, both the district court and the Third Circuit had already held—in a prior litigation brought by the FTC—that the underlying patent lawsuit was “objectively baseless” and a “sham.” 96 F.4th at 377. Here, by contrast, no court has made any such “sham” finding regarding Defendants’ assertion of the ’438 Patent in litigation. To the contrary, Judge McNulty *twice* ruled that J&J’s assertion of its patent in litigation *was not* fraudulent. Judge McNulty held that J&J had a “*triable*” case and “*probable cause* to bring its patent infringement action,” *La. Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, No. 19-cv-14146-KM, 2021 WL 4988523, at *9–10 (D.N.J. Oct. 27, 2021), and Judge McNulty also stated that his ruling on the invalidity of the patent was “a judgment call . . . that could be made differently by another jurist,” Hr’g Tr. 60:13–14, *BTG Int’l Ltd. v. Amneal Pharms., LLC*, No. 2:15-cv-5909-KM (D.N.J. Nov. 5, 2018), ECF No. 581 (“BTG Hr’g Tr.”). Further, Relator has conceded that he is not pleading a sham litigation. ECF No. 424-1 at 12.

Nor can *Abbott Laboratories* be extended here to invoke the crime-fraud exception based on underlying conduct beyond sham litigation, such as Relator’s allegations about Defendants’ actions before the USPTO. According to Relator, the ’438 Patent’s ultimate invalidation by the courts means that “it has been conclusively established” that Defendants’ statements to the USPTO regarding commercial success in support of the patent were “false.” ECF No. 422 at 7. Relator is just wrong. When a patent is found invalid as obvious, that reflects a judicial determination that

“the differences between the subject matter [of the patent’s claims] and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art” 35 U.S.C. § 103(a) (pre-AIA). It also reflects a judicial determination that evidence of objective indicia (*e.g.*, commercial success) did not establish non-obviousness. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (objective indicia “must be weighed in every case”). That determination is what happened here. Judge McNulty expressly described the legal merits of that question as close and a “judgment call,” BTG Hr’g Tr. 60:13–14, and he even “recognize[d] that this abiraterone product [i.e., Zytiga in combination with prednisone] *has enjoyed commercial success*,” *BTG Int’l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 387 (D.N.J. 2018) (emphasis added). None of the courts to consider the patent ever expressed or implied that Defendants made any false statements to the USPTO in seeking the patent. Nor did any of the well-lawyered and sophisticated parties in those suits ever lodge an inequitable conduct claim based on any purportedly false statements to the USPTO.³

Nor did any of the courts express or imply that Defendants’ legal arguments in support of the patent were frivolous. Even if the courts had done so—which they did not—that still would not be sufficient to invoke the crime-fraud exception. There is a vast gulf between having lost in court and having committed fraud. Indeed, were Relator’s argument accepted, the losing party in every court action, indeed the moving party on every rejected motion, would be susceptible to claims of fraud. That is simply not the law. In fact, courts frequently have rejected the proposition that even *frivolous* legal claims are necessarily fraudulent. *See, e.g., Oxxford Clothes XX, Inc. v.*

³ The failure of any party to raise that claim in litigation is telling. “Inequitable conduct is the ‘atomic bomb’ of patent law . . . [that] renders the entire patent unenforceable” and cannot be cured. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (citations omitted). If Relator’s fraud arguments had even a hint of truth (and they do not), every generic manufacturer would have been incentivized to raise them in an inequitable conduct claim in the underlying Hatch-Waxman patent litigation.

Expeditors Int’l of Wash., Inc., 127 F.3d 574, 578 (7th Cir. 1997) (“[A] frivolous claim is not . . . a fraudulent claim.”); *In re EEOC*, 207 F. App’x 426, 434 (5th Cir. 2006) (per curiam) (crime-fraud exception does not apply where “only evidence of fraud” was that the defendant’s lawsuit was “frivolous”); *In re St Johnsbury Trucking Co.*, 176 B.R. 122, 125 (S.D.N.Y. 1994) (same). Here, as Judge McNulty’s statements establish, Defendants’ litigation claims were not even in the same neighborhood as frivolous.

III. Relator’s request is excessively broad and needlessly late.

Finally, Relator’s ever-evolving demands of this Court and the Special Master make clear that his attempts to obtain *in camera* review of privileged documents are nothing more than a “groundless fishing expedition[.]” *Zolin*, 491 U.S. at 571. Relator has failed to identify evidence of fraud after more than three years of discovery in which Defendants have produced 6 million pages of documents and 21 witnesses for deposition. Failing at each of those turns, Relator sought to dump more than 900 privileged documents on the Special Master’s desk, with just days left in fact discovery, in the hopes the Special Master would find something interesting that all the other discovery tools available to Relator have not. *See* ECF No. 346. Although Relator ultimately narrowed his initial request to a review of 50 documents on a “priority” basis—which the Special Master already completed—Relator is still ultimately demanding *in camera* review of all 965 documents, claiming he is entitled to any privileged document that falls within any one of six different categories that go well beyond theories pled in his complaint. *See* ECF No. 424-1 at 13–14.

Notably, Relator does not include his requests for documents in these six categories in his cover motion or his proposed order to the Court. *See* ECF No. 424-2. Further, Relator did not make these requests to the Special Master in the first instance, as he is required to do for all discovery disputes. *See* ECF No. 331. But in any event, no such categories of documents exist.

All six are premised on Relator's supposition that Defendants' patent counsel acted with fraudulent intent. As Defendants' prior brief establishes, that claim lacks any support in the law or the facts. For all the reasons articulated by the Special Master in his two orders (*see* ECF Nos. 374, 424), the Court should deny this request.

CONCLUSION

Based on the foregoing, Relator's Motion for *In Camera* Review should be DENIED.

March 24, 2025

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